

REMARKS

Applicants respectfully request entry of the above claim amendments. Applicants appreciate the Examiner's comments regarding claims 86 and 87 and believe the amendments incorporate the suggested subject matter into the independent claims as suggested by the Examiner. Basis for the amendments may be found in for instance on Page 3, lines 26-28 and lines 32-33 (cartilage extract prepared by enzymatic proteolytic hydrolysis comprising a glycosaminoglycan), Page 4, lines 5-7 (synthetic forms of a glycosaminoglycan), Page 5, lines 26-29 (lycopene or tomato extract comprising lycopene), Page 7, lines 28-29 (natural of synthetic source of the hydrophilic antioxidants), Page 8, lines 7-8 and 24-26 (polyphenols as a hydrophilic antioxidant and hydrophilic antioxidants extracted from grape seed) and throughout the application as originally filed. Applicants respectfully submit that no new matter is added by these claim amendments.

Objections

The Examiner has objected to claim 65 as lacking an intended use. Applicants respectfully disagrees that an intended use is required as the Examiner suggests and are aware of no such requirement. Applicants believe claim 65 is properly defined as a composition according to the claimed components. However, in the interest of advancing the case Applicants have added dependent claim 91 which wherein the composition is formulated "for oral administration". Additionally, claims 68 and 75 have been amended to correct the spelling errors.

Claim Rejections under 35 U.S.C § 112

The Office Action alleges claims 65-66, 68, 70-71, 78 and 81-88 are indefinite because of the term "extract". Amended claim 65 now defines the groups of active compounds and methods of extraction for the compounds. Applicants have defined the extract in terms of the active principle found in the extract which allows a person skilled in the art of extraction sufficient guidance as to how to obtain the active principle. Additionally, one skilled in the art of extraction and from reading the specification would recognize different solvent and solvent combinations suitable for extracting the active principle from natural sources. The rejection is respectfully traversed.

With regard to claim 68 the phrase "Cardus marianum" has been deleted from the claim and therefore the rejection is believed moot. Similarly, claim 70 has been deleted, and claims 81 and 82 have been amended to address the Examiner's concerns. Therefore the rejection is believed moot.

The Examiner purports that claim 88 is rendered vague due to the phrases "slow release" and "normal release". Applicants submit the phrases are generally accepted and used by persons skilled within the pharmaceutical arts. See, for instance the application on page 14, lines 32- page 15, line 14, wherein Applicants discuss various formulations. Furthermore, the phrases are characterized in the Pharmacopoeias of United States and Europe. As such, Applicants respectfully submit that these amendments obviate and/or traverse the remaining §112 rejections.

Claim Rejections under 35 U.S.C. § 102

Initially, Applicants point out it is unclear which claims have been rejected under §102 as allegedly being anticipated by Greenberg (US 5,569,458), however Applicants submit that the amendments to claims 65, 68-71, 73-75, 78-84, and 86-87 have obviated the rejections submitted by the Examiner. Generally, the claimed invention is directed toward a composition comprising i) cartilage extract obtainable by enzymatic proteolytic cleavage, wherein said cartilage extract comprises a glycosaminoglycan, synthetic forms of a glycosaminoglycan extractable from cartilage by enzymatic proteolytic cleavage, or a combination thereof; ii) an extract containing one or more hydrophilic antioxidants, wherein said one or more hydrophilic antioxidants comprises polyphenols and esters thereof, synthetic forms of polyphenols and esters thereof extractable from grape seed, or a combination thereof; and iii) lycopene, a tomato extract comprising lycopene, or a combination thereof. "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." (*Electro Med. Sys. S.A. v. Cooper Life Sciences*, 32 U.S.P.Q.2d 1017, 1019 (Fed. Cir. 1994)). Applicants respectfully submit that Greenberg does not define a composition comprising lycopene as defined in amended claim 65 and the specific groups of active compounds from cartilage and grape seed extracts.

Applicants provide further explanation as to why the new and amended claims even further define the invention over the applied prior art. Greenberg defined a composition comprising a number of minerals, vitamins and extracts. In terms of anti-oxidants, Greenberg

lists that the formulation further includes at least one anti-oxidant selected from the group of beta-carotene, vitamin B6, pantothenic acid, selenium, vitamin E, zinc, L-glutathine, DL-methionine, SOD glutathine peroxidase, coenzyme Q10, silymarin, and proanthocyanidin (column 5, line 55- column 6, line 2). Again, this exhaustive list does not comprise lycopene.

Moreover, the list of ingredients for the formulation of a typical formulation according to Greenberg (column 2, lines 63-67 to column 3, lines 5-28), despite disclosing over 30 active ingredients, does not disclose lycopene or chondroitin sulfate as active ingredients. Furthermore, lines 29-46 of column 3, which further lists possible agents, does not disclose lycopene or herbs from which lycopene may be extracted. Therefore Greenberg does not disclose lycopene or herbs from which lycopene may be extracted as an ingredient in the formulations of the invention.

Furthermore, Greenberg does not specifically disclose that lipophilic and hydrophilic antioxidants must both be present in the formulation. For at least the foregoing reasons, Applicants respectfully request removal of these rejections in view of Greenberg.

Claim Rejections under 35 U.S.C. § 103

The Office Action states that the claims 65-85 and 88 are allegedly obvious over Greenberg in view of Bombardelli et al. (EP 0,659,402) and Kosbab (WO 00/07607). Initially, Applicants point out that the amended claims have incorporated the subject matter of claims 86 and 87. Applicants respectfully disagree and traverse this rejection.

As stated by the Federal Circuit, “a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant’s disclosure. *Id* at 493. *See also* M.P.E.P. § 2142. Applicants provide further explanation as to why the new and amended claims even further define the invention over the applied prior art.

As discussed, *supra*, Greenberg does not disclose a composition comprising lycopene and has not recognized the advantage of lycopene in the treatment of various skin conditions. Greenberg does not teach that compositions comprising lycopene results in an improved treatment of various skin conditions. Furthermore, Greenberg does not teach formulations containing both hydrophilic and lipophilic antioxidants. The person skilled in the art would not consider the teachings of Greenberg when developing a composition for skin improvement. As stated by the Examiner, Greenberg does not teach combining lycopene explicitly with both hydrophilic antioxidants and the lipophilic antioxidant, lycopene.

Lycopene is a claimed component of the invention. None of the cited documents cite the use of this component with both hydrophilic antioxidants and glycosaminoglycans obtainable from cartilage or the beneficial synergistic affect of compositions for improving skin conditions by improving cartilage maintenance and synthesis.

Bombardelli does not teach the advantages of lycopene for treating skin conditions. Moreover, Bombardelli does not teach the advantage of combining lipophilic antioxidants such as lycopene and hydrophilic antioxidants for improving various skin conditions. The teachings of Bombardelli are in a technical field removed from the present invention and address altogether different health issues. Moreover, Bombardelli does not disclose a composition comprising cartilage or a glycosaminoglycan-containing extract, or synthetic forms of glycosaminoglycans, nor the advantage of such compositions for treating skin conditions. Additionally, there is no teaching in Bombardelli of increased collagen synthesis or decreased formation of advanced glycosylation end products resulting from a composition comprising (lycopene) lipophilic and hydrophilic antioxidants. Rather, Bombardelli discloses a combination of hydrophilic antioxidants with lycopene.

Kosbab discloses a composition for skin improvement comprising cartilage or chondroitin sulphate and antioxidant comprising extracts. More particularly, Table 2 discloses components considered to be involved in the maintenance and/or synthesis of collagen. These components include ascorbic acid, bioflavonids, chondrotin sulfate, glucosamin sulfate, cartilage, polyphenol and extracts from pine bark, bilberry, grape seed, ginkgo biloba. Furthermore, Kosbab teaches that carotenoids such as lutein, zeaxanthin, beta carotene and lycopene functions as antioxidants to control oxidative stress, angiogenesis, help regulate the level of homocysteine

and possesses anti-tumor activity. According to Table 2 of Kosbab, lycopene does not have a collagen maintenance or collagen synthesis function.

Kosbab's explicit absence of associating lycopene in collagen synthesis or maintenance in the context of the invention by Kosbab may actually be viewed as teaching away from the use of lycopene in compositions for skin improvement.

The combined teachings of Greenberg and Bombardelli would not motivate the skilled person to develop a composition comprising glycosaminoglycan, polyphenols and lycopene, since none of the documents provide the motivation to the skilled person to combine hydrophilic antioxidants, lipophilic antioxidants with lycopene for improving various skin conditions. Similarly, the combination of the teaching Greenberg and Kosbab will not direct the person skilled in the art to a composition comprising lycopene in combination with cartilage when developing compositions for skin improvement. In conclusion Greenberg, Bombardelli et al. and Kosbab do not teach the combination of lycopene and glycosaminoglycan in compositions for skin improvement. Furthermore, they do not disclose the synergistic effects of a composition comprising glycosaminoglycan; polyphenols and esters thereof; and lycopene. Thus, the present invention is non-obvious from the combined teachings of the cited documents.

The fact that a claimed product is within a broad field of the prior art and one might arrive at it by selecting specific items and conditions does not render the product obvious in the absence of some directions or reasons in the prior art for making such selections. (*Ex parte Kuhn*, 132 U.S.P.Q. 359 (Pat. & Tr. Office Bd. App.)(1961)). Similarly, in *In re Baird* the court recognized that a compound within the scope of a generic formula which encompasses more than 100 million compounds does not make obvious the motivation for the selection of specific compounds. (29 U.S.P.Q.2d 1550, (1994)). Prior art references in combination do not make an invention obvious unless something in the prior references would suggest the advantage to be derived from combining their teachings. *In re Sernaker*, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). In the present case, the Examiner has done no more than find the separate elements of the present invention and argue that broad disclosures which would require specific selection and experimentation to achieve the current invention, render the present invention obvious.

A combination may be patentable whether it be composed of elements all new, partly new or all old. *Rosemont, Inc. v. Beckman Instruments, Inc.*, 221 U.S.P.Q. 1, 7 (Fed. Cir. 1984).

There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Lindemann v. Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984). *Interconnect Planning Corporation v. Feil, et al.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In the present case there is no such motivation. One cannot pick and choose among individual parts of assorted references as a mosaic to recreate a facsimile of the claimed invention. *AKZO N.V. v. International Trade Commission*, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986). *Uniroyal v. Rudkin-Wiley*, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988).

If motivation were to exist, which it does not, one would not be motivated to select specific characteristics Greenberg, Bombardelli et al. and Kosbab to arrive at the claimed invention. Further, one would not be motivated to utilize the claimed compositions for skin improvement. Indeed, the statutory standard of 35 U.S.C. §103 is whether the invention, considered as a whole, would have been obvious to one of ordinary skill in the art, not whether it would have been obvious for one of ordinary skill in the art to try various combinations. *Akzo N.V. v. E.I. duPont de Nemours*, 1 U.S.P.Q.2d 1705, 1707 (Fed. Cir. 1987). Where the prior art discloses no particular preference for the component claimed from among a number of other components disclosed in a reference, i.e., where there is no disclosure within the prior art that would have led the routineer to make the critical selections to arrive at the claimed composition, the court found a rejection for obviousness could not be sustained. *Ex parte Wittpenn*, 16 U.S.P.Q.2d 1730, 1731 (PBAI 1990).

For the reasons set forth above, Greenberg, Bombardelli et al. and Kosbab do not render obvious the claims. As stated in the M.P.E.P., “[i]f an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.” See M.P.E.P. § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)).

Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

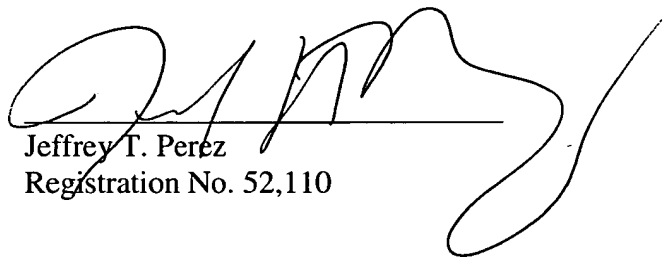
Applicant respectfully submits that the application is in condition for allowance and respectfully requests a notice of allowance for the pending claims. Should the Examiner determine that any further action is necessary to place this application in condition for allowance the Examiner is kindly requested and encouraged to telephone Applicant's undersigned representative at the number listed below.

The Commissioner is hereby authorized to charge fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required now or hereafter, or credit any overpayment, to Deposit Account No. 50-0206.

Respectfully submitted,

Date: November 17, 2003

By:

A handwritten signature in black ink, appearing to read 'Jeffrey T. Perez', is written over a horizontal line. The signature is stylized with large loops and a long horizontal stroke extending to the right.

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